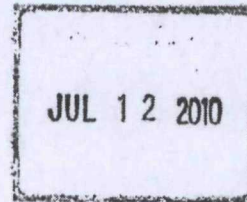




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Wendy A. McCombie
Agent for Sterilex Corporation
Lewis and Harrison
122 C Street, N.W., Suite 740
Washington, DC 20001



SUBJECT: Ultra Kleen Solution I
EPA Registration Number: 63761-3
Application Date: March 11, 2010
Receipt Date: March 19, 2010

Dear Ms. McCombie:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is unacceptable due to the concerns listed below:

- Addition of Biofilm claims for Public Health Uses

You have proposed to add public health pesticidal claims to this product. Your biofilm claims based on field study data are not acceptable for the following public health sites: pools, spas, whirlpool bathtubs, Jacuzzis and foot baths. You may delete these use sites/directions for use and resubmit this application to make other changes to the labeling.

Your product is mixed with Ultra Kleen Solution II (containing sodium carbonate) which is not registered for use as a pesticide. Should you decide to pursue the use of Ultra Kleen Solution I for public health claims, you must register Ultra Kleen Solution II (containing sodium carbonate) as a pesticide.

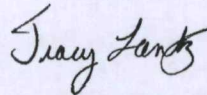
In addition, if you pursue the addition of public health pesticidal claims for this product, you must submit a protocol for review in support of these claims followed by

an amendment based on data produced according to this protocol once such protocol has been reviewed and accepted. This protocol would be subject to an external review by an AD expert panel, subject to PRIA II time frames and fees: A522, \$10,500, 15 month review time frame. Should a method be accepted, you may submit supporting data and revised labeling as an A570.

General Comments

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



for

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

